MAR 3 1 2004

K033074

INION
Intelligent Solution

510(k) SUMMARY

Product: Inion GTR™ Biodegradable Membrane System
Date: 09/19/2003

MANUFACTURER

Inion Ltd.
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FIN-33520 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Coordinator
Lääkärinkatu 2
FIN-33520 Tampere
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DEVICE NAME

Trade name: Inion GTR™ Biodegradable Membrane System
Common/Usual Name: Biodegradable GTR™ Membrane and Tacks

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification panel: Dental
Regulatory Class: Unclassified
Bone Filling Augmentation Material has been assigned Product Code LYC.

PREDICATE DEVICES

(1) Atrix Laboratories, Inc.; Atrisorb®Bioabsorbable Guided Tissue Regeneration (GTR) Barrier (K955838)
(2) W.L. Gore & Associates, Inc.; Gore Resolut™ XT Regenerative Material (973594) and Gore OsseoQuest Regenerative Membrane (K973594)
(3) Geistlich- Pharma; Resor Pin Resorbable Membrane Pin (K972817)

INTENDED USE

1.1 Indications for Use

The Inion GTR™ Biodegradable Membrane System is indicated for the surgical treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures (e.g. class II furcation defects, intrabony defects and recession type defects), for pre-implant and peri-implant surgery and for covering bone defects and empty sockets.

1.2 Contraindications

The Inion GTR™ Biodegradable Membrane System should not be used in patients with active or potential infections, patient conditions including limited blood supply, when patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse), and in load bearing indications unless used in conjunction with traditional rigid fixation. There are currently no known additional contraindications to the use of the Inion GTR™ Biodegradable Membrane.

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion GTR™ Biodegradable Membrane System, intended to be used as a barrier membrane in GTR (guided tissue regeneration) and GBR (guided bone regeneration), consists of membranes and separately available tacks made of degradable co-polymers composed of L-lactic, D-lactic, glycolic acid and trimethylene carbonate.

The membrane provides a barrier that is stable over 8-12 weeks in vivo. Bioresorption takes place within one to two years. NMP (N-methyl-2-pyrrolidone) plasticizer temporarily softens the membrane and is used to facilitate the handling and shaping of the membrane. Plasticizer is added into the membrane just before the operation.

The membranes are fastened in position by using separately available Inion GTR™ tacks or commercially available resorbable sutures. The Inion GTR™ Biodegradable System tack looses its strength over 12-26 weeks *in vitro* with complete strength loss and resorption within two to four years.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion GTR™ Biodegradable Membrane System is substantially equivalent to those of the previously accepted and clinically successfully used biodegradable GTR membranes and tacks intended for similar indications.

Inion GTR™ Biodegradable Membrane System Atrisorb®Bioabsorbable Guided Tissue Regeneration (GTR) Barrier (K955838), Gore Resolut™ XT Regenerative Material and OsseoQuest Regenerative Membrane (K973594) and Resor Pin Resorbable Membrane Pin (K972817) have the same principles of operation and very similar design characteristics. Extensively testing demonstrates that the device is substantially equivalent to the predicate ones. Differences between the Inion GTR™ Biodegradable Membrane System and predicate devices do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2004

Ms. Hanna Marttila
Regulatory Affairs
Inion Limited
Lääkärinkatu 2
FIN-33520 Tampere
FINLAND

Re: K033074
Trade/Device Name: Inion GTR™ Biodegradable Membrane
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: NPK
Dated: January 13, 2004
Received: January 15, 2004

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033074

Indications for Use

510(k) Number (if known): K033074

Device Name: Inion GTR™ Biodegradable Membrane

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033074